DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 19, 2014

Arthrosurface Incorporated
Ms. Dawn J. Wilson
Vice President of Quality and Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K142942
Trade/Device Name: HemiCAP Humeral Head XL (HHXL) Articular Resurfacing System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: November 18, 2014
Received: November 20, 2014

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): _____

Device Name: HemiCAP® Humeral Head XL (HHXL)
Articular Resurfacing System

Indications For Use:

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 510(k) Summary

HemiCAP® Humeral Head XL (HHXL) Articular Resurfacing System

Special 510(k): Device Modification

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory Tel: 508.520.3003 Fax: 508.528.4604 dwilson@arthrosurface.com

Establishment Registration Number:	3004154314
Date of Preparation:	October 9th, 2013
Confidentiality:	Reference Section 3
Proprietary Name:	HemiCAP® Humeral Head XL (HHXL) Articular Resurfacing System
Common Name:	Hemi-Shoulder Resurfacing Prosthesis
Device:	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Regulation Description:	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulation Number:	888.3690
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	HSD

Intended Use

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

Device Description

The HemiCAP® Humeral Head XL (HHXL) Articular Resurfacing System incorporates an articular resurfacing component and a taper post fixation component that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

Substantial Equivalence Information

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the HemiCAP® Humeral Head XL Articular Resurfacing System is substantially equivalent in indications and design principles to the following predicate devices, which have been previously cleared by the FDA:

- The sponsor's previously cleared Contoured Articular Prosthetic (CAP) Humeral Head Resurfacing System (K023096, Cleared on 04/10/2003)
- Biomet Inc.'s Copeland Resurfacing Heads (K003044, Cleared on 12/13/2000 and K010664, Cleared on 04/05/2001)
- DePuy Orthopaedics Inc.'s Global CAP Resurfacing Replacement Shoulder (K031971, Cleared on 09/24/2003)

The fundamental scientific technology of the proposed device has not changed relative to the predicate device (K023096).

- Has the same Indications for Use,
- Has the same operating principle,
- Is manufactured using the same material,
- Has the same shelf life,
- Is packaged and sterilized using the same materials and processes.

In support of this submission, the following non-clinical tests and analyses have been performed on the Subject Device:

- Static Compression Testing
- Cyclic Fatigue Testing
- Axial Disassembly Testing
- Torsional Testing

The results have demonstrated the safety and effectiveness of the HemiCAP® Humeral Head XL (HHXL) Articular Resurfacing System Implants along with substantial equivalence to the predicate device (K023096).